

**BRITT M. BORDEN M.D.**  
SPINAL INSTRUMENTATION SURGERY

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December 2, 1999

Document Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fisher's Lane. Room 1061  
Rockville, Maryland 20852

RE: **Docket # 97N-484S**

Dear Sir/Madam:

I have recently become aware of proposed regulation of allograft tissue that appeared in the Federal Register September 30, 1999. Please note that the safety and efficacy of human bone for interbody spine fusion has been proven by 60 years experience by thousands of surgeons and patients.

I do not think that testing allograft bone based on its shape will add anything to patient outcomes, and it will be likely to result in withdrawal of these products from the market due to the cost of such testing. I encourage you not to adopt any wording of regulations which would result in testing of allograft tissue.

Sincerely,



Britt M. Borden, M.D.

BMB/jmh

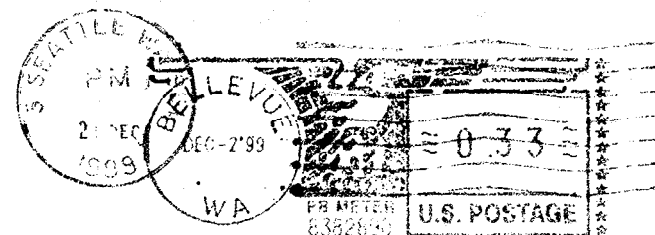
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